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RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	03/19/2010

QA

1006

Administrative Procedure

1001

Controlling Suspect/Counterfeit Items Procedure

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1.0 Purpose

The purpose of this procedure is to describe the actions necessary to manage Suspect Counterfeit Items (S/CI) upon discovery.

2.0 Scope

All new and existing items, equipment, products or parts at Fermilab are within the scope of this document.

3.0 Applicability

This procedure applies to Fermilab line management, division/section/center (D/S/C) S/CI Coordinators, employees, subcontractors, and users, Senior Safety Officers (SSO's), Laboratory ES&H Committee Chair, Procurement Department, and the Office of Quality and Best Practices (OQBP).

4.0 Responsibilities

- 4.1 The Fermilab Director
- Approves the S/CI policy as part of Director's Policy #10, Quality Assurance
- Holds management accountable for implementation of, and compliance with, this program and its implementing procedures
- Appoints OQBP as the Fermilab site S/CI Coordinator
- 4.2 Heads of Divisions/Sections/Centers
- Ensure compliance with this procedure for their areas of responsibility including flow down of requirements and awareness
- Provide the necessary resources as appropriate to implement this procedure
- Ensure individuals within their D/S/C are trained in S/CI where required
- Appoint S/CI Coordinators for each D/S/C

4.3 The Office of Quality and Best Practices

- Oversees the Fermilab S/CI Program and serves as the site S/CI Coordinator
- Provides support to line management and S/CI Coordinators in resolving open S/CI issues
- Recommends what notification to the DOE Office of the Inspector General and the DOE Site Office is required
- Forwards requests for subject matter expert (SME) guidance to the relevant laboratory ES&H subcommittee chairs when S/CI discoveries or reports require a laboratory response.
- Provides periodic status reports to the Fermilab Assurance Council, the Laboratory Director, line managers, and others as appropriate
- Maintains training materials and works with ES&H and D/S/C training to provide training
- 4.4 Employees, Subcontractors and Users
- Receive training in S/CI awareness as it pertains to their work
- Notify their immediate supervisor when a potential S/CI is discovered
- Follow applicable FESHM policies and procedures
- 4.5 Supervisors, Construction Coordinators, and Task Managers
- Notify appropriate line management and S/CI Coordinator of potential S/CI
- Refer to this procedure when a potential S/CI is discovered

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- Determine training requirements
- Ensure that S/CI-related information is flowed down to all affected employees, subcontractors and users working under their direction either through formal training or transfer of information (with records maintained) by an S/CI-trained Fermilab employee

4.6 Division/Section/Center S/CI Coordinators

- Work with the supervisor, engineering, OQBP, Procurement or other subject matter expert, to document and resolve reported S/CI
- Maintain an S/CI log
- 4.7 Senior Safety Officer for Division/Section/Center
- Respond to requests for safety related evaluation of S/CI
- Inform local S/CI Coordinator and OQBP when the result of a safety related evaluation of S/CI identifies a safety risk
- 4.8 Laboratory ES&H Committee (FESHCOM) Chair
- Bring requests from OQBP for SME guidance on S/CI to the relevant subcommittee for review and response
- Provide the laboratory's response to requested S/CI reviews
- Elevate to other ES&H subcommittees or the laboratory ES&H committee if necessary

4.9 Procurement

- Incorporate technical requirements that are a part of or attached to the relevant requisition into the subcontract
- Contact subcontractor and ensure that Fermilab's S/CI concerns are documented in Fermilab's subcontract file

5.0 Procedure for Controlling Identified S/CI

This section describes the step by step procedure for managing S/CI upon identification (See the flowchart in Appendix I). For a discussion of items which are prone to be counterfeited see Appendix II.

Note: Fermilab personnel SHALL NOT contact the supplier of a potential S/CI without concurrence from OQBP.

Note: A nonconforming item is not automatically suspect and should be managed using existing nonconforming / discrepant items procedures unless there is evidence suggesting that it meets the definition of a suspect item or counterfeit item in section 7. Appendix II provides guidance on identification of S/CI.

- 5.1 An individual identifies a potential S/CI, stops work associated with the S/CI and notifies their immediate supervisor or other line manager.
- 5.2 The supervisor/line manager notifies the local Senior Safety Officer (SSO) if there is a risk to ES&H, segregates S/CI where practicable, and notifies the local D/S/C S/CI Coordinator. The SSO will begin an investigation to determine the immediate ES&H-related risks the potential S/CI poses.

IF it is not practicable to segregate S/CI (due to the nature of the item or because it is installed), THEN line management will make provision to ensure that others in the area are

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made aware of the presence of S/CI. The supervisor/line manager ensures that work associated with the S/CI is not resumed until an investigation has been conducted and the S/CI has been dispositioned by engineering or other subject matter expert.

IF the S/CI is installed, THEN notify appropriate management to request assistance with the investigation from engineering or other subject matter expert. The engineer or other subject matter expert will determine S/CI disposition, including notifying the SSO of a risk to ES&H not already reported.

IF notified by a supervisor/line manager, THEN the local SSO follows applicable FESHM policies and procedures and notifies the local S/CI Coordinator and OQBP if his/her investigation concludes that there is a safety risk associated with the S/CI.

IF the D/S/C S/CI Coordinator receives a "response required" notice from OQBP of S/CI discovered elsewhere, THEN he/she will contact the appropriate line management to ensure an inspection is conducted. IF S/CI is discovered during the inspection THEN the S/CI Coordinator and line management, ensure that it is managed in accordance with these procedures.

IF the S/CI notice from OQBP does not indicate "response required", THEN it is for awareness only and local management will determine if any action is required.

- 5.3 The D/S/C S/CI Coordinator ensures that S/CI is segregated or other provisions applied as noted in step 2, and indicates the S/CI status with an S/CI Tag to prevent further use. Where tagging is not practicable, application of a "safety purple" paint appropriate for the materials and conditions is acceptable. The S/CI Coordinator updates and maintains an S/CI log which includes the unique S/CI log number, pertinent information about the item, including status.
 - 5.3.1 The S/CI Tag has two sides. The S/CI Coordinator completes the side labeled HOLD, indicates the S/CI log number and reason the item is suspect and contact information. The other side of the S/CI Tag is reserved for disposition by the responsible engineer or subject matter expert.

IF the application of an S/CI Tag or paint is not practicable, THEN the D/S/C S/CI Coordinator will contact OQBP to determine the appropriate action to prevent further use. An S/CI log number is still assigned and logged even in the event alternative markings are used as directed by OQBP.

5.4 The D/S/C S/CI Coordinator coordinates the investigation with line management and other staff, updates and ensures the S/CI log and supporting materials contain adequate information.

Line management determines if the potential S/CI is nonconforming or if the specification is in question.

IF the item is confirmed to be nonconforming THEN follow existing nonconforming / discrepancy procedures and continue to the next step.

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IF the item is not nonconforming relative to the requestor's requirements, but still considered to be a potential risk or issue THEN the D/S/C S/CI Coordinator notifies OQBP. OQBP will determine if further notifications are necessary. Examples include high strength shackles or high strength bolts with no manufacturer's code and no clear purchasing requirement for a manufacturer's code.

Note: Nonconforming procedures should require identification and quarantine of all like items.

5.5 The D/S/C S/CI Coordinator and line management (with SME participation, as appropriate) complete an investigation and reach a conclusion indicating whether the S/CI status is confirmed. Two conditions must be met to conclude that the S/CI status of an item is confirmed; 1) It must be nonconforming to requirements specified in procurement documents, and 2) its documentation, appearance, performance, material, or other characteristics <u>may have been</u> knowingly misrepresented. See the Definitions section.

IF the status is no longer considered S/CI, THEN continue with existing nonconforming procedures including disposition by engineering or other subject matter expert.

IF the item is still considered to be a potential risk or issue, although no longer considered S/CI, THEN the D/S/C S/CI Coordinator notifies OQBP. OQBP will determine if further notifications are necessary.

IF the status is confirmed S/CI or still in doubt, THEN locate, tag and quarantine all items with the same item identification from the same procurement. The D/S/C S/CI Coordinator notifies OQBP and provides copies of supporting materials upon request. In this case S/CI remains in quarantine pending further instruction from OQBP.

5.6 Disposition of S/CI is recommended by engineering or other subject matter experts based on evaluation of the likelihood of injury to personnel, damage to the environment, damage to other equipment, and other technical and operational considerations. The S/CI Coordinator will ensure that OQBP, line management, and SSO's are advised of the recommended disposition. The recommended disposition requires OQBP approval before implementation.

One or more of the dispositions below may be selected:

- Replace immediately
- Replace at next scheduled maintenance
- Replace at next planned maintenance outage
- Implement additional controls
- Continue to use in place
- Retain sample S/CI for training

IF the disposition of installed items is other than replace immediately THEN the responsible engineer or subject matter expert completes the side of the S/CI Tag labeled DISPOSITION. This side includes a section for "Review date" which must be completed to indicate when the S/CI issue or the material itself should be re-examined.

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Note: It is expected that when S/CI are replaced the S/CI Tag is removed, they are destroyed, and the S/CI log entry closed out. The exception to S/CI destruction is whether the OQBP wishes to retain the item for training purposes. In the event where S/CI are destroyed, disposal must be completed in a manner to prevent reuse and records of destruction shall be retained. Records are retained by BSS, Property & Inventory Control in accordance with "Department of Energy Administrative Records schedule 4, Item 1 which established a two-year retention schedule for property disposal records. For offsite destruction, contact the Business Services Section, Property and Inventory Control Manager. Destruction of S/CI materials considered hazardous is handled in accordance with applicable laws, regulations DOE directives and FESHM 8021.

5.7 Results of dispositions shall be recorded in the log.

6.0 Records

S/CI Log Records of disposition Records of destruction

7.0 Review Cycle

This procedure shall be reviewed for accuracy and relevance on at least a three year cycle

7.1 Document Owner OQBP QA Manager

7.2 Reviewers
OQBP Head
Division/section/center S/CI Coordinators
Procurement Manager

7.3 Approver OQBP

8.0 Policy and Program Documents

Directors Policy #10, Quality Assurance

1001 Fermilab Integrated Quality Assurance (IQA) Chapter 10, Suspect/Counterfeit Items

1006 Suspect/Counterfeit Items Program

1006.1002 Suspect/Counterfeit Items OQBP Procedure

Fermilab Environment Safety & Health Manual (FESHM) Chapter 3010, Significant and Reportable Occurrences

9.0 Definitions

Counterfeit items are nonconforming items whose documentation, appearance, performance, material, or other characteristics <u>are</u> knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Nonconforming items are items that do not meet specified requirements.

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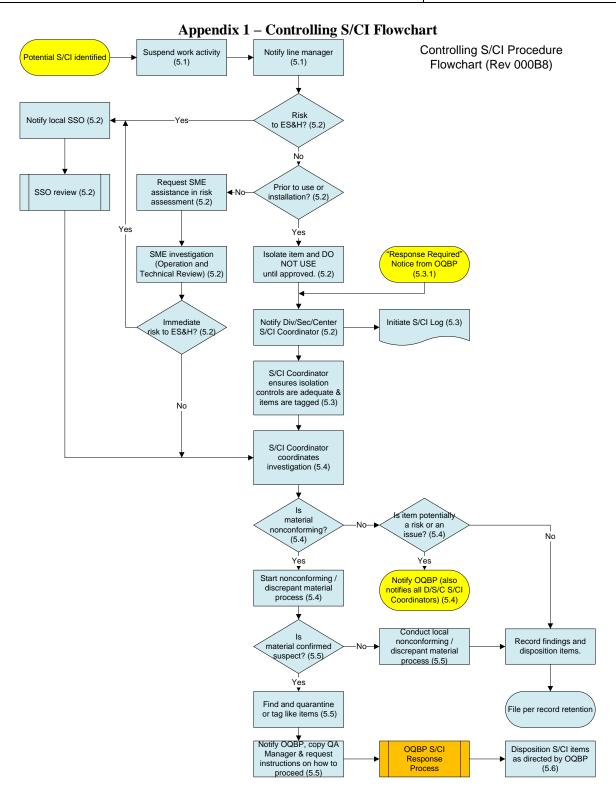
Suspect items are nonconforming items whose documentation, appearance, performance, material, or other characteristics <u>may have been</u> knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Note: By definition, for an item to be considered S/CI officially it must first be nonconforming to specified requirements. Therefore all confirmed S/CI are nonconforming items but all nonconforming items are not necessarily S/CI.

10.0 References

DOE O 414.1C *Quality Assurance* – Contractor Requirements Document, Attachment 2 Section 4 – DOE-Wide Suspect/Counterfeit Item Prevention Process DOE G 414.1-3- *Suspect Counterfeit Items Guide*

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Appendix II- Identifying S/CI

Items prone to be counterfeited:

- Moderate or low-cost, high-demand / high turnover use items
- Items easily copied by secondary market suppliers
- Items that often bypass the vendor (seller or manufacturer) and are drop shipped to the requestor
- Items that are not typically inspected
- Items that are sold by un-authorized distributors

Typical S/CI are:

- Used, rebuilt, or reconditioned items sold as new
- Fraudulently marked or labeled as being manufactured by a recognized reputable company, or certified by a regulatory or certifying agency
- Manufactured with misrepresented inferior materials, or processes that create a potential for failure and exposure to hazards.

Industrial types of items, materials, parts, and components that have been counterfeited include, but are not limited to:

- Hoists, as well as other hoisting, lifting, and rigging equipment
- Valves, pipe, pipe fittings, plates, couplings, plugs, spacers, nozzles, supports, hangars, and flanges
- Preformed metal, elastomers (O-rings, seals), spare replacement kits from suppliers other than the original equipment manufacturer, weld-filler material, diesel generator speed governors, pumps
- Fasteners: Metallic screw, nut, bolt, or stud having internal or external threads with a nominal diameter of 1/4 inch (6 mm) or greater. Washer that is through-hardened or represented as meeting a consensus standard that calls for through-hardening, and that is grade identification marked or represented as meeting a consensus standard that requires grade identification marking. e.g., J429 standard for automotive and related industries below grade 5 (plus grade 8.1 studs) no grade-mark required. However, all bolts and screws shall bear the manufacturer identification symbol.
- Electrical equipment and devices, including circuit breakers, transformers, fuses, relays, resistors, capacitors, semiconductors, connectors, switch gear, power supplies, inverters, transmitters, and motors
- Metal plates, bars, shapes, channel members, and other structural items
- Welding rods and electrodes

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The listing of commercial grade items that have been counterfeited is extensive. Following is a partial listing:

- Batteries: household, camera, and cell-phone
- Extension cords
- Surge suppressors
- Fire extinguishers
- Automotive components, including oil filters and brake pads
- Computer components, semiconductors, software
- Pharmaceuticals

Disclaimer

This appendix provides information on individual components identified as suspect or suspect/counterfeit. Without additional information, the manufacturers or suppliers identified should not be considered as to have engaged in any wrongdoing. It is not necessarily a negative reflection on a supplier or manufacturer if their products are reported as suspect/counterfeit items (S/CI). Reputable manufacturers and suppliers have a vital interest in preventing the manufacture and distribution of S/CI associated with their names. The supplier or manufacturer may have been victimized and is pursuing S/CI associated with its products in an aggressive, prudent, and professional manner to get these items off the market. Therefore, each particular case must be examined on its own merit without making premature conclusions about the fault or culpability of the manufacturer or supplier whose name is associated with the S/CI.

The following is an update to the Suspect Item Indicator list found in DOE G 414.1-3 and the DOE Suspect/Counterfeit Item Awareness Training manual.

SUSPECT ITEM INDICATOR LIST

Note: This information alone does not constitute an item or material as being S/CI. Further research, such as a review of purchase orders, specifications, and certification / documentation is required before an item can be categorized as S/CI.

I. GENERAL INDICATORS

Visual Inspection

- Nameplates, labels, or tags have been altered, photocopied, or painted over; are not secured well; are unusual in location and method of attaching; have incomplete data; or are missing.
- Preprinted labels that show typed entries.
- Item has wear marks or scratches on external surfaces.
- Obvious attempts at repair or beautification have been made, such as excess painting or wire brushing; evidence of hand-painting (touch-up), painted stainless steel; non-ferrous metals (e.g., copper, brass, bronze) are clean and bright indicating recent polishing.
- Handmade parts are evident; gaskets are rough-cut; shims and thin metal part edges show evidence of cutting or dressing by hand tools (filing, hacksaw marks, tin snips, or nippers).
- Assembled items fit poorly.
- Metallic items are pitted or corroded.
- Heat discoloration marks.
- Casting markings have been ground off and the item has been re-stamped with other markings.
- Configuration is not consistent with other items from the same supplier or varies from that indicated in supplier literature or drawings.
- Inconsistency between vendor (seller or manufacturer) name on the item, and the shipping container.

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Visual Inspection continued

- Nameplates attached with inconsistent fasteners, such as screws instead of rivets, or a combination of rivets and screws.
- Nameplates attached in a different location than normal.
- Warning labels with grammatical errors and conflicts with information found elsewhere on the packaging.
- Nameplates missing manufacturer's standard markings, stamps, or logos, and with irregular stamping or inconsistent type (font).
- Inconsistent appearances of items in the same shipment.
- Shipping boxes / totes containing mixed batch numbers, expiration dates, and uniform product codes (UPC).
- The item or component matches the description of one that is listed on a suspect item list (e.g., DOE Suspect/Counterfeit Fastener Headmark List).
- Unusual packaging and boxing of items. Packaging is inconsistent with the manufacturer's normal packaging or documentation requirements.
- Questionable or meaningless numbers on the item(s) or packaging.
- Signs of weld repairs
- Country of origin is China¹, Taiwan, India, Korea, or Mexico.
- Underwriters Laboratories (UL) marks missing one or more of the four elements (UL trademark, the word LISTED in capital letters, product identity, and a control number)²; a UL mark on the package but not on the product.

Procurement

- Quoted price for the item is unusually discounted or low.³
- Unusual disclaimers, or denials, of responsibility for the accuracy of the test results, etc.
- The supplier is not a manufacturer's authorized distributor.
- Dimensions of the item are inconsistent with the specification requested on the purchase order, and those provided by the manufacturer at the time of the shipment.

- 1 In 2003, more than 66% of goods seized at ports of entry into this country were traced to China. What are Counterfeiting and Piracy Costing the American Economy. National Chamber Foundation, 2005.
- 2 Refer to http://www.ul.com/ace/fake.html
- 3 There have been reports of counterfeiters raising prices to just below OEM levels in order to prevent such concerns. http://fleetowner.com/mag/fleet_counterfeit_parts_buyer/index.html

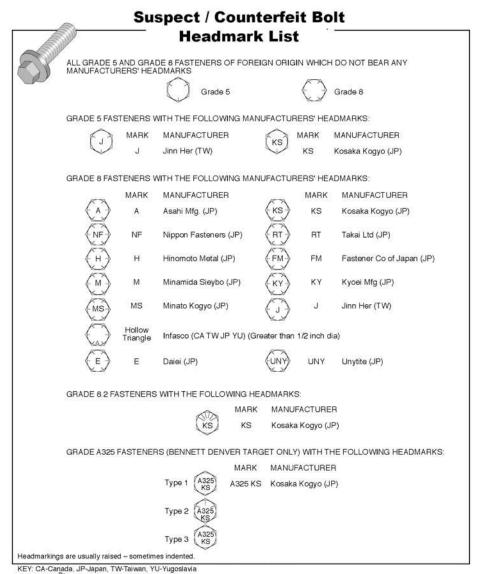
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II. DOCUMENTATION

Documentation may be suspect or fraudulent when:

- The use of correction fluid or correction tape is evident.
- Type style, size, or pitch change is evident.
- Documentation is not signed or initialed when required.
- It is excessively faded or unclear (indicating multiple, sequential copying), or data is missing.
- The name of the document approver, or title, cannot be determined; the document has missing or illegible signature, initials; the approvers name and signature does not match.
- Technical data is inconsistent with code or standard requirements.
- Certification or test results are identical between items when normal variations should be expected.
- Document is not traceable to the items procured.
- Corrections are not properly lined-out, initialed and dated.
- Documentation is not delivered as required on the purchase order, or is in an unusual format.
- Lines on forms are bent, broken, or interrupted indicating data has been deleted or exchanged by "cut and paste".
- Handwritten entries are on the same document where there is typed or preprinted data.
- Text on page ends abruptly and the number of pages conflicts with the transmittal.
- Data on a single line is located at different heights.

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ANY BOLT ON THIS LIST SHOULD BE TREATED AS DEFECTIVE WITHOUT FURTHER TESTING.

The above list was prepared by the U.S. Customs Service after extensive testing of many samples of fasteners from around the United States. If found, consider any of these headmarks as S/CI.

In many cases, a new counterfeit fastener has roughly the same physical strength as the graded fastener it mimics, but does not meet the chemical composition or heat treatment requirements specified in consensus standards. As a result, it will stretch, exhibit metal fatigue, or corrode under less harsh service than the genuine fastener.

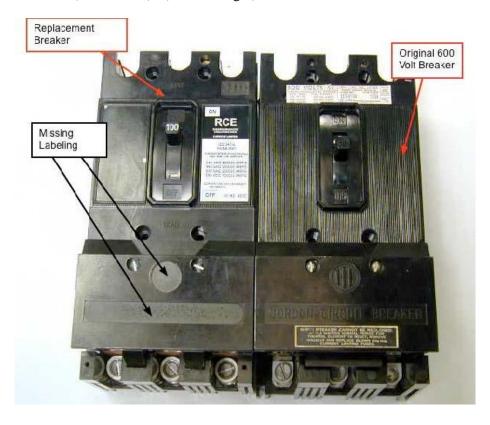
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Fasteners - Bolts.

Suspect/Counterfeit SAE Grade 5 (ASTM A 449) bolts. (Photo on left) From the left -the first three are missing the required manufacturer's symbol, and the fourth bolt has the "KS", Kosaka Kogyo insignia. All four are on the DOE S/C bolt headmark list (Enclosure 1). (Photo on right) failed fork lift bolt.



Circuit Breakers.

 $Suspect\ indicators-missing\ information$

Left – Used 600 volt, 100 amp breaker sold as "new".

Right – Original breaker

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Fuses.

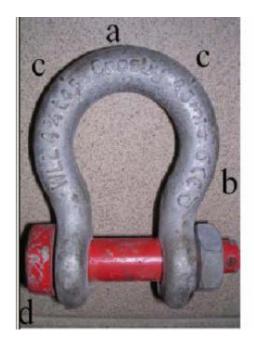
S/CI - Used internal components within 600 volt, 100 amp breaker sold as "new and unused".



Hook, lifting.

S/CI - Altered working load limit (WLL) marking.

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Shackle.

Counterfeit on right. Authentic Crosby on left. a) Crosby name embossed per Crosby logo, b) should see CE mark, c) 45-degree angle markings, d) pin stamped on head with traceable ID number (www.imca-int.com/safetyflashes)



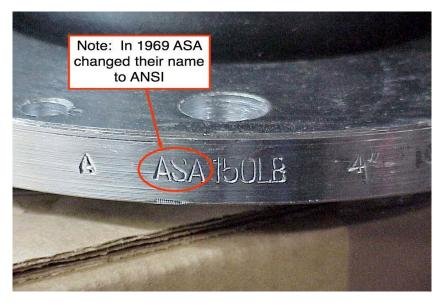
Shackle.

S/CI – Trademark violation. 6-1/2 Ton rated screw pin shackle, minus any manufacturer's name or logo, and country of origin. The red colored screw pin is a Crosby Group trademark.

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Flange. Suspect indicator - Hand stamping



Flange.

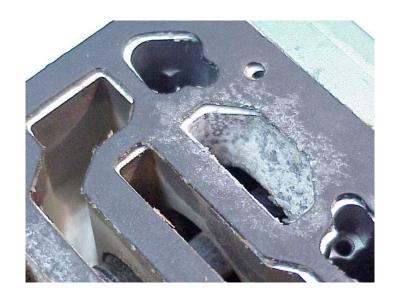
Suspect Indicator – Meaningless information; ASA is a reference to an obsolete consensus standards organization.

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Label.

Suspect indicator - Worn label with missing information on a "new" air-dryer valve.



Valve, internal. S/CI - Internal corrosion of an air-dryer valve sold as "new".

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Extension cords. S/CI - Underwriters Laboratories (UL) Inc. issued an alert regarding 25 and 50 ft. cords. The cords are marked as UL listed and having 14 gauge wire. These have not been approved by UL and the wire size is actually significantly undersized, leading to potential fire hazards. http://www.ul.com/newsroom/notices.html



Sprinkler heads, fire protection. S/CI - UL issued two alerts in 2006 regarding Chinese manufactured sprinkler heads having counterfeit UL marks. http://www.ul.com/newsroom/notices.html

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Batteries.

S/CI – "Copper Top" trademark violation and confusingly similar name of the manufacturer "Duracell". Counterfeit batteries present a higher risk of malfunction; constructed without adequate vent holes (safety feature), and often contain mercury - a heavy metal that damages the central nervous system when ingested and can harm the environment when the batteries are discarded

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Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft with most formatting changes accepted. A1 to A2 Updated draft – eliminated intermediate form, replaced with S/CI log only – changed initiation of log to S/CI Coordinator. Updated name and number scheme. Other changes noted with change tracking on. A2 to A3 reconcile OQBP comments.	000 A3	07/18/08
Jed Heyes	Final reconciliation and promotion	000 B	07/23/08
Jed Heyes	Updated for lab safety subcommittee role. Clarified when response to OQBP notices are required	000 B1	08/19/08
Jed Heyes, Kurt Mohr	Updated based on formatting comments from Business Services Section & Jeff Cotton & consistency with revisions to the S/CI Program.	000 B2	11/07/08
Kurt Mohr	Changed Sect. 8 (Policy and Program) reference to "FIQMP" to "IQA"	000 B3	11/13/08
Kurt Mohr	Revised for consistency with SCI Program based on S/CI team review	000 B4	12/9/08
Kurt Mohr	Revised for consistency with S/CI Program, changes based on input from Joe Collins & Greg Mitchell	000 B5	12/10/08
Kurt Mohr	Revised Appendix 1 flowchart for consistency with rev B4 & B5 changes. Added allowance for painting as S/CI identification method and OQBP approval of disposition recommendation	000 B6	12/15/09
Kurt Mohr	Minor revisions based on S/CI Coordinator reviews 12/09	000 B7	1/26/10
Kurt Mohr, Jed Heyes	Minor revisions based on S/CI Coordinator Meeting 1/27/10 and: Revised list of those with program responsibilities in 3.0 Applicability. Clarified supervisory role for program flowdown and expanded application to Construction Coordinators & Task Managers in 4.5. Relocated paragraphs regarding OQBP "response required" notification from 5.3.1 to 5.2. Clarified example in 5.4. Changed initial notification path to insert OQBP before full Coordinator notification in 5.4 & 5.5. Added SME's to investigating team in 5.5. In 5.6 - Specified completion of "review date" section of tag, records retention responsibilities & disposal of hazardous S/CI material. 7.2 Updated following input from Bruce Chrisman	000 C	3/16/10

SUBJECT:	Controlling Suspect/Counterfeit Items Procedure	NUMBER:	1006.1001
RESPONSIBILITY:	Quality Assurance Manager	REVISION:	001
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	03/19/2010

Author	Description	Revision	Date
Jed Heyes	Removed watermark. Minor changes to match the program document.	001	03/18/2010